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COST (In Millions)	FY 2003	FY2004	FY2005	FY 2006	FY 2007	FY 2008	FY 2009
Total Program Element (PE) Cost	157.861	149.105	147.533	147.975	146.604	144.888	125.745
Biological Warfare Defense Program BW-01	157.861	149.105	147.533	147.975	146.604	144.888	125.745

(U) **Mission Description:**

(U) DARPA's Biological Warfare Defense project is budgeted in the Applied Research Budget Activity because its focus is on the underlying technologies associated with pathogen detection and remediation. This project funds programs supporting revolutionary new approaches to biological warfare (BW) defense and does not duplicate efforts of other government organizations.

(U) Efforts to counter the BW threat include developing barriers to block entry of pathogens into the human body (including unique methods for rapid air and water purification), countermeasures to stop pathogen and chemical consequence and to modulate host immune response, medical diagnostics for the most virulent pathogens and their molecular mechanisms, biological and chemically-specific sensors, advanced decontamination and neutralization techniques, and integrated defensive systems, including detection of chemical and biological agents in sealed containers at entry points of facilities. Program development strategies include collaborations with pharmaceutical, biotechnology, government, and academic centers of excellence.

(U) **Program Accomplishments/Planned Programs:**

	FY 2003	FY 2004	FY 2005
Unconventional Therapeutics	46.578	41.596	37.533

(U) This thrust is designed to take unique and unconventional approaches for developing therapeutics for a wide variety of threat pathogens that might be encountered in a biological warfare attack. Countermeasures (e.g., Anti-Virals/Immunizations, Anti-Bacterial/Anti-Toxins and Multi-Purpose) under development include: (1) multi-agent therapeutics against known, specific agents and (2) therapeutics against virulence pathways shared by broad classes of pathogens. Specific approaches include developing a new class of antibiotics targeted towards enzymes

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essential to bacterial pathogen survival, identification of virulence mechanisms shared by pathogens, development of therapeutics targeting these mechanisms, efficacy testing in cell cultures and animals, and advanced non-toxic decontamination strategies, including decontamination from radiological poisoning. The development of an artificial immune system through 3-dimensional tissue engineering will provide rapid, in vitro assessments of novel countermeasures against unique DoD threat agents.

(U) Program Plans:

- Transition three (3) small molecule antibiotic technologies to the United States Army Medical Research Materiel Command (USAMRMC) for continued development.
- Transition two (2) BioWarfare and clinical decontamination technologies to advanced development and commercialization.
- Transition multivalent Dengue DNA vaccine to USAMRMC-Infectious Disease for advanced testing and clinical development.
- Transition novel target discovery platform for late stage anthrax therapeutics to United States Army Research Institution of Infectious Diseases (USAMRIID).
- Transition Botulinum Toxin and Superantigen toxin therapeutics to USAMRMC for advanced testing.
- Transition novel modified red cell scavenging technology to USAMRMC.
- Transition technology for good manufacturing practices (GMP) production of vaccines and antibodies in plants as an alternative to traditional manufacturing procedures.
- Develop and mature technology to treat or prevent infections caused by biological warfare pathogens; discover new targets that would protect against engineered organisms.
- Identify new approaches that will significantly shorten the drug development process and increase the efficiency in identifying lead compounds, using in silico modeling and bioinorganic approaches.
- Discover broad-spectrum therapeutics that attack fundamental and common biochemical processes in bacteria and/or viruses.
- Establish a common test-bed for efficacy, safety and drug metabolism in FDA validated models.
- Develop regulators of critical enzyme systems that prevent viral and/or bacterial replication.
- Develop antibody surrogates against agents of interest.
- Explore mechanisms that induce innate immunity and early protection.
- Explore mechanisms of cellular control that are used by pathogens to mask identification.
- Explore the role of plasmid, phage and virus in controlling adaptive mechanisms in bacteria that result in pathogenic phenotypes.

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- Assess the feasibility of accurately identifying "drug-able protein targets" from the known primary DNA structure-using novel computing approaches.
- Rapidly identify novel vaccine targets for bacteria or viruses.
- Develop a rapid response capability for developing candidate DNA vaccines from newly discovered or engineered pathogens.
- Develop new strategies/treatments for late stage biological warfare (BW) infections.
- Demonstrate the inherited and environmentally determined risk to BW pathogen infections as a tool in developing unique treatments.
- Develop a data analysis approach to efficiently identify DNA sequences for gene-chip diagnosis of viral and bacterial infections.
- Develop therapeutic approaches that target host biochemistry to deny a broad range of pathogens (within or across classes) the opportunity to infect and cause disease thereby radically changing the prophylactic and therapeutic approach of the DoD to protecting the warfighter in hazardous environments.
- Develop new data analysis capability to interpret biosignature data in individuals incubating a disease.
- Develop an integrated in vitro human immune system, capable of supporting rapid and cost effective vaccine development and testing through the establishment of tools necessary for in vitro fabrication of three dimensional tissue constructs, bioscaffolds and bioreactors.

	FY 2003	FY 2004	FY 2005
Acceleration of Anthrax Therapeutics	26.000	4.000	0.000

(U) This thrust will accelerate promising anthrax therapeutics (antibodies, immunostimulatory approaches and late stage treatment) into the FDA regulatory process and file an Investigative New Drug application, which would allow the first human safety trials.

(U) Program Plans:

- Validate an alternative primate model to replace the current Rhesus monkey model for testing inhalation anthrax therapeutics.
- Establish preclinical primate drug safety and metabolism capability for testing of candidate drugs.
- Demonstrate preclinical efficacy of anthrax antibiotic candidates.
- Demonstrate preclinical efficacy of immunomodulator drugs against inhalation anthrax.
- Demonstrate preclinical efficacy of late stage anthrax therapeutic candidates.

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– Demonstrate preclinical efficacy of a novel adjuvant for currently approved anthrax vaccine (improve safety and speed of vaccination).

	FY 2003	FY 2004	FY 2005
External Protection	5.500	6.000	10.000

(U) This program is developing and demonstrating a variety of external protection technologies to protect soldiers from the hazards of chemical, biological and radiological attack. This includes novel water purification approaches, new approaches for air filtration and purification, and the detection and cleaning of surfaces contaminated by an attack.

(U) Program Plans:

– Develop, test and transition to the Services a water purification pen capable of disinfecting 300 liters of non-brackish water and a desalination hand pump able to provide 1 liter of sweet water from brackish or seawater in 5 minutes.
– Develop and test a micro fibrous gas adsorbent material with 10-times the gas life and one-half the pressure drop of the current C2A1 gas mask canister.
– Design, develop, test and transition to the Services regenerable air filtration and purification systems suitable for extended personal and collective warfighter and citizen protection.
– Develop new approaches for self-decontaminating surfaces.
– Design, develop and demonstrate systems to detect contaminated surfaces down to the human toxicity levels, and to remove the contamination to below those levels.

	FY 2003	FY 2004	FY 2005
Advanced Diagnostics	5.000	7.730	12.000

(U) In the early stages, many illnesses caused by biological warfare (BW) agents have flu-like symptoms and are indistinguishable from non-BW related diseases. Early diagnosis is key to providing effective therapy. The advanced diagnostics efforts will develop the capability to detect

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the presence of infection by biological threat agents, differentiate them from other pathogens (including those of non-BW origin), and identify the pathogen even in the absence of recognizable clinical signs and symptoms (i.e., while the pathogen numbers are still low). Novel approaches including the use of breath and advanced mathematical analysis will be examined.

(U) Program Plans:
- Evaluate hyperspectral strategies for early clinical diagnosis of infection and other medical issues that affect soldier performance.
- Validate and demonstrate strategies for rapidly generating new probe panels for relevant sample types (in breath, blood and other biological samples).
- Evaluate and demonstrate multiplexed pathogen detection in microliter samples.
- Validate and demonstrate strategies for rapid detection of pathogens based on biomarkers for early indication of infection or exposure.
- Develop new mathematical and diagnostic approaches to interpret biosignature data from individuals to determine if there will be a change in physiological status from health to disease and vice versa. Use these data to identify the kind of disease and need for treatment.

	FY 2003	FY 2004	FY 2005
Sensors	37.654	42.000	48.000

(U) Organic Based Sensors.

- A unique approach for sensors is the use of cellular, tissue, and organism-based sensors for the rapid detection of biological threats. These cellular and tissue-based sensors have the ability to respond to both known and unknown threats, determine live versus inactivated threat status, and report functional consequences of exposure (mechanisms of action).

(U) Program Plans:
- Define limits of detection, false alarm rates, and system variability for cell based amplification and detection of biological threat agents.

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- Design and develop sample preparation, processing and delivery methods to maximize bioavailability and activity of the sample and minimize the effect of interferents and fluidics.
- Develop a multitude of critical physiological-based assays that provide information on cellular and tissue responses to a wide variety of threat agents of interest to the Department of Defense.
- Confront the statistical and computational challenges associated with the collection of extremely large datasets from biological sources to include developing software algorithms, models, and other bioinformatic tools aimed at determining acceptable parameters of performance and understanding response profiles.
- Demonstrate the utility of prototype cell and tissue based biosensors in operationally relevant scenarios, including environmental monitoring and medical diagnostics.
- Demonstrate advantages and utility of novel materials developed from mimicking natural biological materials and systems.

(U) Time-of-Flight Mass Spectrometer (MALDI).

- DARPA is developing a small time-of-flight mass spectrometer using Matrix Assisted Laser Desorption/Ionization (MALDI). This approach will enable fluid-free analysis of whole proteins, and therefore make possible fast, reliable biosensors with low false alarm rates and greatly reduced logistics tails.

(U) Program Plans:
- Design and build MALDI time-of-flight (TOF) brassboard system.
- Develop biological warfare agent signature libraries and measure clutter characteristics for MALDI TOF brassboard system.
- Design, build, and test optimized MALDI TOF prototype.
- Develop and validate end-to-end MALDI TOF performance model.

(U) Handheld Isothermal Silver Standard Sensor (HISSS).

- The overall goal of DARPA's Handheld Isothermal Silver Standard Sensor (HISSS) program is to develop a sensor that is capable of detecting the entire biological warfare threat spectrum (bacteria, DNA viruses, RNA viruses and protein toxins) with the same "silver standard" specificity as current laboratory techniques, but in a fast, reliable, handheld unit. Today, this standard is achieved for DNA and RNA threats using polymerase chain reaction, which is slow because of the associated temperature cycling. For proteins, the standard is

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met using Enzyme Linked Immunosorbent Assay (ELISA), which requires skilled laboratory technicians to complete. The equipment required for these tests is bulky and difficult to use under field conditions. Under HISSS, DARPA will develop fundamentally new ways to exploit previously developed identification mechanisms (DNA and RNA primers, protein antibodies) in an integrated, isothermal system that will allow a single, handheld sensor to detect the full range of BW threats.

(U) Program Plans:
- Develop isothermal assays for DNA, RNA and protein toxins and demonstrate a false-alarm rate equivalent to the current laboratory technology.
- Develop a microfluidics testbed for assay optimization and system integration.
- Develop stabilized reagents for fieldability.
- Design and build a prototype HISSS device.
- Characterize HISSS prototype in laboratory and operational environments.

(U) Triangulation Identification for Genetic Evaluation of Biological Risk (TIGER).

- Most nucleic acid based sensors search for an exact sequence match to some unique part of each pathogen. This requires a unique set of primers and probes for every target pathogen; it also means that the sensor can only determine whether that specific (portion of the) target pathogen is present. DARPA is developing a new kind of DNA-based sensor that searches out the universal parts of the genetic code and looks for species-specific variation between these regions. The sensor is called Triangulation Identification for Genetic Evaluation of Biological Risks (TIGER). It will enable a universal sensor for all pathogens that also holds the promise of detecting the presence of never-before-seen (bio-engineered) agents.

(U) Program Plans:
- Design and build "gold standard" laboratory instruments for high volume data collection of agent and background signatures.
- Develop and validate end-to-end performance model.
- Carry out proof-of-concept analysis, and preliminary performance prediction in clutter.
- Design, build and test fieldable prototype(s) optimized for environmental and/or diagnostics applications.
- Characterize prototype behavior in operational environments.

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(U) Spectral Sensing of Bio-Aerosols (SSBA) (formerly Electromagnetic Energy).

- Active probing of bioaerosols with electromagnetic (EM) energy holds the promise of extremely fast, and potentially long-range, detection and identification of bio agents. Only a small portion of the EM spectrum is exploited in today's trigger sensors (e.g., optically based particle sizers, sometimes enhanced with fluorescence measurements). However, anecdotal evidence suggests that other portions of the spectrum may offer substantial improvement in trigger sensors, as well as potentially agent-specific discrimination capability. DARPA is investing in this approach, beginning with cross-spectrum data collection and performance models, followed by prototype sensor development.

(U) Program Plans:
- Develop bioaerosol testbed and standardized data-collection protocols.
- Investigate spectral response of chemicals unique to BW agents (e.g., picolinic acid in anthrax spores).
- Collect data, and develop performance model, for concepts that exploit a wide part of the electromagnetic (EM) spectrum (e.g., Raman scattering, terahertz spectroscopy, laser-induced breakdown spectroscopy, coherent Raman anti-Stokes spectroscopy, IR/photoacoustics, etc.).
- Downselect to most promising concepts; design, build, and test prototype sensor.
- Characterize prototype behavior in operational environments.

	FY 2003	FY 2004	FY 2005
Immune Buildings	29.329	29.329	21.000

(U) DARPA is developing technologies for integrated defensive systems to be employed in military buildings to protect and respond to the emerging threat of aerosolized Chemical, Biological and Radiological (CBR) releases. The approach is to modify and augment the infrastructure of buildings to allow them to sense and defeat an attack by bio or chem agents in real-time. The program has three goals: to protect the human inhabitants from the effects of the agents; to restore the building to function quickly after the attack; and to preserve forensic evidence for treatment of victims, if necessary, and for attribution. The DARPA focus is on the challenging problem of protection from internal releases of agent, where active and timely control of airflow is required to prevent a building's HVAC system from spreading the agent throughout the

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building. To enable such building-protection systems, DARPA is developing component technologies such as optimized filtration systems, advanced neutralization techniques, and remediation techniques appropriate to biological, chemical, and radiological decontamination. In addition, DARPA is investigating the systems-level issues of integrating and optimizing such active systems, including the integration and adaptation of sensors, as well as the simulation of threat events and emergency responses. These efforts have used full-scale test facilities to determine the effectiveness of protection components and the optimal architectures for protection. These systems are being transitioned to a full-scale demonstration of a complete building protection system at a military installation and will also leave behind a software tool for the design and optimization of building-protection systems for other military buildings.

(U) Program Plans:

- Develop high-payoff component technologies in the areas of filtration, neutralization, and decontamination; and mature sensors as necessary for this active Defense application.
- Demonstrate performance of component technologies in full-scale application.
- Optimize active protection system concepts, and demonstrate performance.
- Characterize the selected demonstration site facility, and design, build, and test an active protection system optimized for that site.
- Integrate existing models, and develop new models as required, into a software toolkit that enables performance predictions for protective architectures in other buildings.
- Validate toolkit predictions in test beds, at demonstration site, and elsewhere as required.

	FY 2003	FY 2004	FY 2005
Chem Bio Defense (CBD) Portal Security	0.000	0.000	3.000

(U) There is an enormous payoff in preventing the release of biological warfare agents (BWAs) and chemical warfare agents (CWAs), rather than trying to minimize the damage they cause once released. For this reason, DARPA is investing in technologies and systems to prevent such materials from entering buildings, either in packages or mail, or as an item hand-carried by a visitor.

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(U) Program Plans:
- Evaluate non-intrusive technologies for destruction of biological agents (e.g., ultrasound, variable frequency microwave and new techniques for X-Ray and gamma irradiation) and/or for the detection of chemical agents (e.g., associated particle neutron elemental analysis, tera-hertz spectroscopy, dielectric spectroscopy, and swept frequency acoustic interferometry).
- Select the most promising approaches, and use laboratory instrumentation to evaluate collateral damage and false alarms. Develop performance model, and carry out system trades.
- Design, build, and test optimized prototype system(s).
- Demonstrate prototype in operational environment, and characterize performance.

	FY 2003	FY 2004	FY 2005
Wide-Area BWA Surveillance	1.000	1.000	0.000

(U) The Wide-Area Biological Warfare Agent (BWA) Surveillance program is investigating effective and efficient BWA surveillance systems for urban environments, such as military bases and transportation centers, to detect a covert aerosol release of a BWA and to determine the approximate release location *before the onset of symptoms in humans*. The program is studying the key architecture trades, including: the appropriate mix of stationary and mobile assets (collectors/samplers and identification sensors); the value of distributed sampling and identification (sensing) versus distributed sampling with centralized identification; the role of layered sensing, such as continuous wide-area surveillance followed by focused/targeted collects for confirmation; the importance of spatial and temporal resolution in enabling backtracking to determine release time and release location; and specialized collection and identification requirements in different environments. These trades are being carried out by modeling covert releases and then analyzing the ability of various architectures (1) to detect the release quickly and (2) to geo-locate the source. The results of these studies provide the basis for the Threat Agent Cloud Tactical Intercept and Countermeasure (TACTIC) program.

(U) Program Plans:
- Conduct trade studies of various potential detection architectures in selected urbanized areas; estimate system performance.
- Develop analytic methods to geo-locate source based on detector output, meteorology, etc.

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Threat Agent Cloud Tactical Intercept Countermeasure (TACTIC)	0.000	0.000	7.000

(U) The TACTIC Program will develop and demonstrate the capability to (1) rapidly detect, discriminate and identify an airborne chemical warfare agent/biological warfare agent (CWA/BWA) battlefield threat at stand-off distances, and (2) use countermeasures to neutralize and/or precipitate the threat before it reaches the targeted troops. This program will investigate identification methodologies including: bead-based assays for biological molecules, fluorescent assays for chemicals, retro-reflector assays for chemical and biological agents; all of which can be interrogated with stand-off optical detectors. To accomplish the removal of the threat, technologies that mimic the seeding of rain clouds will be developed for particulate bio-agents, and technologies that polymerize chemical agent vapor will be investigated. Upon successful demonstration of the identification and removal technologies, a system will be developed to demonstrate the removal of chemical and biological simulant clouds from the battlefield.

(U) Program Plans:

- Investigate potential technologies for CWA/BWA standoff assays that rapidly (within one minute) identify agents.
- Investigate technologies to remove the agent cloud so as to eliminate the threat to unprotected war-fighters.
- Develop models of identification and removal technologies. Carry out systems trades between competing identification and removal technologies.
- Integrate optimal identification and removal components into a prototype system.
- Test prototype system in scaled aerosol test chambers.
- Demonstrate system in full-scale field trials.

	FY 2003	FY 2004	FY 2005
Mission-Adaptable Chemical Sensors (MACS)	0.000	4.000	9.000

(U) At present, Nuclear, Biological, and Chemical (NBC) sensors lack a combination of sensitivity (parts-per-trillion) and selectivity (definite identification of molecular species), shortfalls that yield false alarms or worse, failure to detect at all. This effort (formerly named Mother of All

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Sensor Systems) will develop a sensor, based upon rotational spectroscopy of gases, which will eliminate both problems and will achieve the highest possible sensitivity for unambiguous detection of most chemical species. The program will focus on technology for reduction of size and simplicity of function, for equipment that presently is large and complicated, to achieve portability and simultaneous detection of multiple species. It will solve the presently intractable difficulties of remotely identifying chemical threats, in seconds.

(U) Program Plans:
- Demonstrate and calibrate improved sensitivity of apparatus for selected species.
- Demonstrate fractionation and related improvements to the system for simultaneous identification of multiple species in seconds.
- Demonstrate capability for dramatic reduction in size and weight of original system, with improved detection sensitivity and selectivity.
- Demonstrate feasibility of prototype portable system for field implementation.

	FY 2003	FY 2004	FY 2005
Center for Water Security	1.000	1.000	0.000

(U) Program Plans:
- Established the Center at the University Wisconsin-Milwaukee through engaging essential technical personnel, acquiring state-of-the-art instrumentation dedicated to researching new and highly effective methods of water quality sensing.
- Continue to develop the use of the new methodologies through partnerships with public and private sector agencies to address water security issues related to civilian and military needs.

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	FY 2003	FY 2004	FY 2005
Asymmetrical Products for BWD	2.000	2.000	0.000

(U) Program Plans:
- Continue to develop a technical approach to induce mucosal immunity against BioWarfare (BW) pathogens. Model and synthesize a cytokine-based family of compounds that stimulate mucosal immunity.
- Identify likely cytokine molecules and their combinations that result in resistance to pathogens.

	FY 2003	FY 2004	FY 2005
Desalination Research	2.300	2.550	0.000

(U) Program Plans:
- Continue to develop a non-traditional approach to large-scale desalination of seawater at the ocean shore near available liquid natural gas (LNG) or liquid methane storage facilities, enabling the formation of gas-hydrate-purified, near-potable water ready for final polish by reduced-cost reverse osmosis processes.

	FY 2003	FY 2004	FY 2005
Bioscience Center for Informatics	1.500	0.000	0.000

(U) Program Accomplishments:
- Conducted research directed at the modeling of disease propagation, rapid detection, and the prediction of risks associated with defense against bioterrorism, building upon such capabilities as distributed databases, geographic information systems, bioinformatics, high performance computing, and modeling.

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	FY 2003	FY 2004	FY 2005
Center for Tropical Disease Research and Training	0.000	2.000	0.000

(U) Program Plans:

- Examine *Leishmania* parasites to identify both *Leishmania* and sand fly molecules that may be useful in developing a protective vaccine against leishmaniasis, a serious disease affecting soldiers returning home from Iraq.

	FY 2003	FY 2004	FY 2005
EluSys Heteropolymer System	0.000	1.500	0.000

(U) Program Plans:

- Explore heteropolymer-based drugs in the development of multiple therapeutic candidates for removal and destruction of pathogens, pathogenic proteins, and/or antibodies providing a potential effective treatment for a broad array of diseases.

	FY 2003	FY 2004	FY 2005
HPGe Gamma Ray Detection Technology	0.000	1.000	0.000

(U) Program Plans:

- Develop new technology for gamma ray detection.

	FY 2003	FY 2004	FY 2005
Hand Held Biosensors for Field Detection of Multiple Bioagents CMIM Palm Pilots	0.000	3.400	0.000

(U) Explore use of hand held biosensors for detection of bioagents.

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(U) Program Change Summary: *(In Millions)*

	FY 2003	FY 2004	FY2005
Previous President's Budget	161.956	137.254	138.533
Current Budget	157.861	149.105	147.533
Total Adjustments	-4.095	11.851	9.000
Congressional program reductions	0.000	-1.599	
Congressional increases	0.000	13.450	
Reprogrammings	0.000	0.000	
SBIR/STTR transfer	-4.095	0.000	

(U) **Change Summary Explanation:**

FY 2003 Decrease reflects SBIR reprogramming.

FY 2004 Increase reflects congressional adds for seven biological warfare projects offset by undistributed reductions.

FY 2005 Increase reflects additional funds for programs in Portal Security and Active Countermeasures against chem/bio threats and a new sensor effort.

(U) **Other Program Funding Summary Cost:**

- Not Applicable.